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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,081	09/18/2003	Joseph A. Marino	C516.12-0007	8990

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,081

Applicant(s)

MARINO ET AL.

Examiner

Kathleen Sonnett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/18/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-8 is/are allowed.
- 6) ☐ Claim(s) 1-4 and 9-20 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/22/03, 8/26/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. **Claims 1, 3, 9, 11, 13, 15, 17, and 19** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,960,220. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claim does not mention the limitation of a flexible intermediate zone to center the device. However, this is a well known feature of occlusion devices.

2. **Claims 1, 4, 9, and 12** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27 (for 1 and 4) and 50 (for 9

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and 12), respectively of U.S. Patent No. 6,379,368. Although the conflicting claims are not identical, they are not patentably distinct from each other.

3. **Claims 1 and 9** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,206,907.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

4. **Claims 1 and 9** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20 and 18, respectively of U.S. Patent No. 6,656,206. Although the conflicting claims are not identical, they are not patentably distinct from each other.

5. **Claims 9 and 12** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,960,224. Although the conflicting claims are not identical, they are not patentably distinct from each other.

6. **Claims 1 and 9** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 10/348,701. Although the conflicting claims are not identical, they are not patentably distinct from each.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

7. **Claim 10** is objected to because of the following informalities: claim 10 depends off of itself. Appropriate correction is required. Note also that claims 11 and 12 depend off of claim 10.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claim 12** recites the limitation "the sheets". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Erlebacher et al. (U.S. 5,350,399). Erlebacher et al. discloses an occlusion device comprising a center post (12) having a first and second side, a first set of arms emanating from the second side of the center post and extending toward the first side, a second set of arms emanating from the first side of the center post and extending toward the second side, and first and second sheets attached to the first and second set of arms (Fig. 8-10, col.

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5 lines 57-68). The center post is flexible and the first and second set of arms define a flexible intermediate zone that helps center the device through the interactions of the arms with the tissue surrounding the aperature.

12. **Claim 9, 17, and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by Huebsch et al. (U.S. 5,853,422). Huebsch discloses a center post (18) with a first and second occluding body connected to the center post and first and second arms emanating from the center post and forming a wire network having a flexible intermediate zone to center the device in an aperature (col. 3 line 64-col. 4 line 9). In this case, the occluding body is the covering over the arms (22) (col. 4 lines 21-27). If the aperature is viewed as roughly cylindrical, when the height (responding to the height of a cylinder) of the aperature is greater then the height of the cylindrical center post, the wire arms (22) will press against the sides of an aperature, thereby centering the device within the aperature.

13. Regarding **claim 17**, the support hoops (14, 16) are connected to the first set of arms and first sheet, and the second set of arms and second sheet, respectively.

14. Regarding **claim 19**, the arms are constructed of stranded wire (col. 4 line 1-9).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Erlebacher et al. in view of Gainor et al. (U.S. 6,911,037).). Erlebacher et al. discloses an occlusion device comprising a center post (12) having a first and second side, a first set of support arms emanating from the second side of the center post and extending toward the first side, a second set of support arms emanating from the first side of the center post and extending toward the second side, and first and second sheets attached to the first and second set of arms (Fig. 8-10, col. 5 lines 57-68). Erlebacher et al. fails to disclose a first and second hoop attached to the first set of arms and the first sheet, and the second set of arms and second sheet, respectively.

17. However, Gainor et al. discloses that it is old and well known in the art to include a frame (24), which along with support arms supports a sheet (Fig. 2, 3). Gainor et al. further discloses the device in several different shapes including circular, wherein the frame would be a hoop. The frame supports the edges of the sheet and pulls the sheet taut (col. 4 lines 9-17). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Erlebacher et al. to include a hoop made obvious by Gainor et al. in order to gain the advantage of having the edges of the sheet supported so the sheet is held taut around the edges and cannot buckle in between successive arms.

18. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Erlebacher et al. in view of Amplatz et al. (U.S. 5,944,738). Erlebacher et al. discloses the invention substantially as stated above, but fails to disclose arms that have a bell shape.

19. However, Amplatz et al. discloses that it is old and well known in the art to have wire arms in a variety of shapes, including a bell shape as shown in Fig. 3. Wires in this shape tend to automatically center themselves on the adjacent opening of the defect while tending to pull the discs toward each other (col. 10, lines 39-48). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Erlebacher et al. to include bell-shaped arms made obvious by Amplatz et al. in order to increase the likelihood of the device self-centering and a tighter fit.

20. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Erlebacher et al. in view of Huebsch et al. Erlebacher et al. discloses the invention substantially as stated above, including arms which are made of a material which is resiliently expandable from a collapsed into an expanded position. Erlebacher et al. fails to disclose that the arms are made of stranded wire.

21. However, Huebsch et al. discloses that it is old and well known in the art to use arms that are made from stranded wire. These arms are resiliently expandable from a collapsed position into an expanded position. Therefore, it would have been obvious to one of ordinary skill in the art to use stranded wire arms made obvious by Erlebacher in the invention disclosed by Huebsch et al. because stranded wire arms would provide a resiliently expandable frame.

22. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Erlebacher et al. in view of Schneidt (U.S. 6,174,322). Erlebacher et al. discloses the invention substantially as stated above including sheets attached to the arms, but fails to disclose that the sheets are constructed of non-thrombogenic polyvinyl alcohol foam.

23. However, Schneidt discloses that it is old and well known in the art to include sheets that are constructed of non-thrombogenic polyvinyl alcohol foam on occlusion devices. The non-thrombogenic PVA reduces the risk of a clot associated with the device breaking loose and causing a stroke and the foam sheets immediately block blood flow as soon as they are unfolded during implantation (col. 9 lines 3-19).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention disclosed by Erlebacher et al. to include sheets made of non-thrombogenic polyvinyl alcohol foam made obvious by Schneidt in order to gain the advantages of a reduced risk of clot formation and immediate blockage of blood flow.

24. **Claims 10, 11, and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. in view of Amplatz et al. (U.S. 5,944,738). Huebsch et al. discloses the invention substantially as stated above including stranded wire arms (col. 4, lines 1-2), but fails to disclose arms that have a bell shape. The examiner is assuming that claim 10 was meant to depend off of claim 9.

However, Amplatz et al. discloses that it is old and well known in the art to have wire arms in a variety of shapes, including a bell shape as shown in Fig. 3. Wires in this shape tend to automatically center themselves on the adjacent opening of the defect while tending to pull the discs toward each other (col. 10, lines 39-48). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Huebsch et al. to include bell-shaped arms made obvious by Amplatz et al. in order to increase the likelihood of the device self-centering and a tighter fit.

25. **Claims 12 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. in view of Schneidt. Huebsch et al. discloses the invention substantially as stated above including sheets attached to the arms, but fails to disclose that the sheets are constructed of non-thrombogenic polyvinyl alcohol foam. Examiner is treating occluding bodies of claim 9 as "the sheets" of claim 12 (Note 35 USC 112 rejection for claim 12 above).

26. However, Schneidt discloses that it is old and well known in the art to include sheets that are constructed of non-thrombogenic polyvinyl alcohol foam on occlusion devices. The non-thrombogenic PVA reduces the risk of a clot associated with the device breaking loose and causing a stroke and the foam sheets immediately block blood flow as soon as they are unfolded during implantation (col. 9 lines 3-19). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention disclosed by Huebsch et al. to include sheets made of non-thrombogenic polyvinyl alcohol foam made obvious by Schneidt in order to gain the advantages of a reduced risk of clot formation and immediate blockage of blood flow.

27. **Claim 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlebacher et al. in view of Gainor et al. and in further view of Amplatz et al. The modified device of Erlebacher et al. discloses the invention substantially as stated above, but fails to disclose bell shaped arms or arms made of stranded wire.

28. However, Amplatz et al. discloses that it is old and well known in the art to use bell-shaped arms that are made from stranded wire (Fig. 3 and col. 5 lines 15-36). These arms are resiliently expandable from a collapsed position into an expanded

position. Wires in this shape tend to automatically center themselves on the adjacent opening of the defect while tending to pull the discs toward each other (col. 10, lines 39-48). Therefore, it would have been obvious to one of ordinary skill in the art to modify the modified device disclosed by Erlebacher et al. to include bell-shaped, stranded wire arms made obvious by Amplatz et al. in order to increase the likelihood of the device self-centering and a tighter fit.

29. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Erlebacher et al. in view of Gainor et al. and in further view of Amplatz et al. The modified device of Erlebacher et al. discloses the invention substantially as stated above but fails to disclose non-thrombogenic polyvinyl alcohol foam sheets.

30. However, Schneidt discloses that it is old and well known in the art to include sheets that are constructed of non-thrombogenic polyvinyl alcohol foam on occlusion devices. The non-thrombogenic PVA reduces the risk of a clot associated with the device breaking loose and causing a stroke and the foam sheets immediately block blood flow as soon as they are unfolded during implantation (col. 9 lines 3-19).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention disclosed by Erlebacher et al. to include sheets made of non-thrombogenic polyvinyl alcohol foam made obvious by Schneidt in order to gain the advantages of a reduced risk of clot formation and immediate blockage of blood flow.

Allowable Subject Matter

31. **Claims 5-8** are allowed. The prior art of Amplatz et al., Huebsch et al., and Erlebacher et al. does not disclose or provide the motivation for an occlusion device with arms that extend from one end of the center post, connect to a sheet located at the opposite end of the post, and further connect to a hoop. The prior art only discloses arms that connect to sheets located on the same end of the center post from which the arms extend and the addition of such structure would not be obvious, as it would destroy the method of functioning of the devices as disclosed by the prior art.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCS


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
